

Information Sharing Paper for National Regulatory Authorities (NRAs) on the Refilling of Cosmetic Products

Introduction:

In the 31st meeting of the ASEAN Cosmetic Scientific Body (ACSB), the Philippines presented the concept of cosmetic refilling activity in addressing the global issue on plastics, without compromising product quality and safety. With an aim to develop the guidelines for National Regulatory Authorities (NRAs) of ASEAN Member States (AMS) in ensuring that product quality and safety is maintained during the refilling of cosmetic products, a Technical Working Group headed by the Philippines, Malaysia, and the ASEAN Cosmetic Association (ACA) was tasked by the ACSB.

Objective:

The aim of this document is to serve as a reference or information document for NRAs as they undertake measures to institute the necessary legal and technical infrastructure to allow the refilling of cosmetic products, consistent with the implementation of the ASEAN Cosmetic Directive (ACD) and not to be interpreted as a regulatory requirement, unless otherwise adopted as a rule by the NRA of the AMS.

Nothing in this document shall restrict the NRA from instituting additional regulatory mechanisms to ensure the proper implementation of the ACD in the local context.

Scope:

This document applies to the NRAs and any establishment within their area of jurisdiction engaging in the activity of refilling empty containers with cosmetic products at the point of sale.

Refilling in this document refers to a post-production activity where bulk cosmetic products are used to replenish appropriate empty containers at the point of sale.

Elements:

The NRAs are recommended to institute the following measures for the refilling of cosmetic products. The succeeding sections are arranged as follows:

1. General Guidelines
2. Pre-marketing Measures
3. Post-marketing Measures
4. Responsibilities of the company or person responsible for Conducting the Cosmetic Refilling Activity

5. Labeling Requirements for Refilled Cosmetic Products

General Guidelines:

1. The company or person responsible for placing the product in the local market will continuously comply with existing laws, rules, regulations, and standards of the NRA. Refilled products are expected to fulfil the obligations stipulated under the relevant articles of the ACD as well as other related guidelines developed by the ASEAN Cosmetic Committee (ACC).
2. The company placing the product in the market will ensure that a qualified person with technical knowledge, experience, skill and capabilities shall be assigned to manage its refilling activities.

Pre-Marketing Measures

Any cosmetic products intended to be placed in the ASEAN market will conform to the ACD, its annexes and appendices to ensure product quality, safety, and efficacy in terms of claimed benefits. As such, in the case of cosmetic refilling activity, the NRA must be notified of the bulk cosmetic products for refill intended to be placed in the market.

1. For a bulk cosmetic product intended for refill that has previously been notified as a finished cosmetic product with the same formulation, a new cosmetic product notification (CPN) is no longer required to be secured from the NRA.
2. For a bulk cosmetic product intended for refill that has not yet been notified, a CPN must be secured from the NRA.

Post-Marketing Measures

1. Cosmetic products for refill will be subject to post-marketing surveillance (PMS) activities of the NRA. The Product Information File (PIF) shall be readily available in accordance to Article 8 of the ACD. Technical documents such as methods and results for the challenge test for preservative system, leachability test, etc. in support for product safety and quality should be readily available to the NRA.
2. The company or person responsible for the cosmetic refilling activity will take appropriate measures to ensure that no reselling of the refilled cosmetic product occurs.

Responsibilities of the company or person responsible for Conducting the Cosmetic Refilling Activity

1. The company or person responsible for placing the product in the local market will be responsible for ensuring the safety, efficacy and quality of the cosmetic products for refill, including the monitoring and investigation of adverse events that may arise from using the product.
2. Cosmetic manufacturers may report and coordinate with the NRA on matters of PMS including but not limited to: (a) serious adverse events such as serious injury/illness resulting to hospitalization or death that can reasonably be attributed to the use of the cosmetic product; (b) error in the manufacturing process of the cosmetic product; and/or (c) availability of new scientific information that serves as evidence of the health hazard potential of the cosmetic product.
3. The company or person responsible for the cosmetic refilling activity will be responsible in educating the consumer regarding the product, such as but not limited to, safety information, frequency of re-use of the emptied product container, and proper disposal of emptied product container wastes.
4. The company or person responsible for the cosmetic refilling activity will adhere to the regulatory, safety and quality requirement as outlined in ACD Appendix VI - ASEAN Guidelines for Cosmetic Good Manufacturing Practice (GMP).

4.1. Quality Management System. A quality system may be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organizational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.

4.2. Personnel. The refilling establishment will ensure that there are qualified personnel who are adequately trained in the operations, ensuring protection of the product from contamination and product quality. Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire.

4.3. Premises. The refilling station or area will be suitably located, designed, constructed, and maintained. Effective measures should be taken to avoid any product mix-up, and contamination from the surrounding environment and from pests. The site should be adequately lit, properly ventilated, and easy to clean and sanitize or disinfect.

4.4. Equipment. The equipment for dispensing may be designed and located to suit the refilling operations of the cosmetic products. Equipment should be located to avoid congestion and should be properly identified to assure that products do not become mixed or confused with one another. Equipment should be easily cleaned, and weighing, measuring, testing, and recording,

wherever applicable, should be serviced and calibrated regularly. All records should be maintained.

- 4.5. **Sanitation and Hygiene.** Measures will be undertaken to minimize the risk of microbial contamination and errors in all aspects of refilling operations. There should be an effective cleaning procedure of the equipment and area to avoid build-up of dirt or other conditions that may directly or indirectly affect the quality of cosmetic products. There should be a validated cleaning procedure for the empty containers that is consistently performed prior to refilling to prevent contamination or microbial growth.
- 4.6. **Refilling Operations.** The following will be followed and maintained in the overall operations:
- Batch numbering system
 - Weighing and measurement
 - Labeling and packaging (re-use of product containers with the same product brand, variant or product type is encouraged)
- All standard operating procedures (SOP), data and information should be completely documented, and products should be labeled for proper traceability purposes.
- 4.7. **Quality Control.** The refilling establishment will ensure that the quality of the products meets requirements as specified by the CPN holder or manufacturer.
- 4.8. **Documentation.** Refill operations will have proper documentation such as delivery of bulk cosmetic product, receiving and actual refilling, in the form of a batch refilling record. Verification should be done on the product labeling to avoid mix-ups. Records must be kept for traceability purposes (i.e. batch number, code date, and/or expiry date). This will facilitate investigation should an untoward incident arise.
- 4.9. **Internal Audits.** An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purpose. Such internal audits may also be extended to suppliers and contractors, if necessary. A report will be made at the completion of each internal audit.
- 4.10. **Storage.** Refilling stations may have appropriate storage areas designed to ensure good storage conditions. They should be cleaned, dried and well-maintained. There should be appropriate storage areas to store the empty bottles or containers to prevent contamination. Proper ventilation should follow the storage conditions of the bulk cosmetic product for refill.

- 4.11. **Complaints.** A system for handling complaints may be placed. There will be assigned personnel and a written procedure describing the incident and actions to be taken. Complaints will be recorded in all aspects and properly investigated. The NRA may be informed if the company or person responsible for the refilling activity is considering taking action following possibly faulty manufacture and/or product deterioration, which may lead to serious safety issues.
- 4.12. **Product Recalls.** An effective system of recall of products known or suspected to be defective may be placed. There will be a written instruction to be established accordingly. Recall operations are capable of being initiated promptly. The recall process will be recorded, and a final report issued, including reconciliation between the sold and recovered quantities of the refilled cosmetic products.
- 4.13. **Contract Manufacturing.** The engaging in subcontracting activity of the cosmetic manufacturer with the company or person responsible for the cosmetic refilling activity can be allowed provided that there is a valid contract of agreement with provision on the shared responsibility to assure quality and safety of refilled products with the end-view of protecting the consumers.

Labeling Requirements for Refilled Cosmetic Products

Containers refilled with the cosmetic product should at least have the following particulars printed on the label:

- a. The name of the cosmetic product, and
- b. The refilling batch number.

A designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution

The following remaining mandatory labeling information as listed in ACD Appendix II - ASEAN Cosmetic Labeling Requirement will be made available or accessible through other informative materials including but not limited to leaflets, pamphlets, hang tags, display panel, shrink wrap and QR code:

1. Product Function
2. Instructions on usage
3. Full ingredient listing
4. Country of manufacture
5. Complete name and address of the Local Company Responsible for Placing the Product in the Market
6. Net Content
7. Manufacturing/Expiry Date

8. Special Precautions (if any)
9. Storage Conditions (optional)
10. Date of Refill (optional)
11. Contact details of MAH for product complaints (optional)

References

ASEAN Cosmetic Directive (ACD)

Appendix II - ASEAN Cosmetic Labeling Requirement

Appendix VI - ASEAN Guidelines for Cosmetic Good Manufacturing Practice (GMP)